

**REMARKS**

This is in full and timely response to the above-identified Office Action. The above listing of the claims supersedes any previous listing. Favorable reexamination and reconsideration are respectfully requested in view of the preceding amendments and the following remarks.

Original claims 1 and 3 were rejected under 35 USC § 102(b) as being anticipated by US 6,129,721.

Claim 1 has been amended to include the subject matter of claim 2, which was *not* found by the Examiner to lack novelty in view of this reference.

Applicant therefore respectfully submits that this amendment overcomes the anticipation by the above-mentioned reference.

Original claims 1 to 14 were rejected as being obvious over the ADKIT publication in view of the Teichman et al publication.

Applicant respectfully submits that there would have been no motivation for a man of ordinary skill in the art to combine the two publications, and even if combined, the combination would not result in the invention as presently claimed.

The ADKIT publication is a specialized Otolaryngology publication, and relates to an *in-vivo* endoscopic laser lithotripsy of a proximal parotid duct calculus. In particular, it suggests limited success in using holmium:YAG laser.

This reference states that one successful endoscopic laser lithotripsy was conducted in 1994 by a Spanish group (page 1, 3<sup>rd</sup> paragraph), and a second such procedure no less than 6

years later (i.e., reported in 2001 in the reference) by a different team.

Thus, a man of the art understands that endoscopic laser lithotripsy of the parotid duct is a rare **Otolaryngological** procedure, which has special problems associated with the small, tight nature of the body cavity. These problems were evidently not experienced in similar procedures as applied to larger cavities like in the removal of urinary calculi, which was a very common procedure then.

In contrast, the Tecihman et al publication is a specialized Urology publication, not normally reviewed by specialists in the field of Otolaryngology, and relates, in further contrast, to *in-vivo* comparative testing of an Erbium:YAG laser and a Holmium:YAG laser, in the context of urinary tract calculi. It very specifically attributes the efficiency of the Erbium:YAG laser "as a result of the inherent absorption characteristics of *urinary* calculi at erbium wavelengths and the efficient delivery through *water*" (page 878, right column, 1<sup>st</sup> paragraph). Moreover, it states clearly that the "Er:YAG laser used in the study was a laboratory grade laser in which the design was not optimized for clinical applications" (page 878, left column, 3<sup>rd</sup> paragraph).

Therefore, the two references not only relate to completely different medical specialized disciplines relating to anatomically different parts of the body, in one Holmium:YG laser treatment being extremely rare, while in the other quite common, they also refer to two different types of tests – *in-vivo* versus *in-vitro*, and thus there would be no motivation for a man of ordinary skill in the art to combine the two references.

Further, the composition of urinary calculi is different from that of salivary calculi. Optimal wavelengths for laser ablation may depend on the chemical composition of the calculi (page 877, left column, 5<sup>th</sup> paragraph) and specifically attributes the efficiency of the Erbium:YAG laser "as a result of the inherent absorption characteristics of *urinary* calculi at erbium wavelengths" (page 878, right column, 1<sup>st</sup> paragraph). Thus, there is no indication

whatsoever in the references that comparative results obtained with respect to urinary calculi necessarily read over to salivary calculi.

Further, the ADKIT references teaches away from expensive clinical procedures (page 1, 1<sup>st</sup> paragraph), and the Teichman references discloses that fibers that were used in the in-vitro tests were relatively expensive (page 2, right column, 1<sup>st</sup> paragraph), and a man of the art would thus be deterred from combining the two references.

Furthermore, the Teichman reference admits that the "fragmentation efficiency" of the Er:YAG laser as compared with the Ho:YAg laser, i.e., "defined as laser fluence may not be clinically relevant" (page 878, left column, 2<sup>nd</sup> paragraph), and again demotivates a man of the art to combine this reference with the ADKIT reference.

In addition, it is to be noted that in the Taichman reference, carrying out tests in-vitro where the calculi were placed in "beakers full of water" (page 1, right column, second paragraph), while providing a possible comparable environment for the calculi in the context of large cavities associated with urinary calculi, are far removed from the in-vivo environment of salivary duct calculi, and may render the test meaningless in such a context.

In fact, the Teichman et al publication fully teaches away from using Erbium lasers for small body cavities, particularly when considered with the teachings of the ADKIT publication.

As clearly stated in the Teichman et al publication, page 876, left column, 1<sup>st</sup> paragraph, Holmium:YAG lasers work by means of a photothermal mechanism, in which the stone compositions are heated by the laser till they fragment. In the second paragraph, it is stated that optical energy is more efficiently absorbed by urinary calculi at the wavelength associated with an Erbium:YAG laser.

In page 2, right column, 4<sup>th</sup> paragraph, this reference clearly states that "as optical energy

is absorbed the stone surface temperature is increased". This, taken with the previous paragraph above, implies that use of an Erbium:YAG laser in the restricted volume of a small body cavity such as the salivary duct, for example, would result in rapid heating thereof to a temperature much higher than would be achieved by a Ho:YAG laser. This suggests to a man of the art that using such a laser in the context of a very small body cavity may cause substantially damage to the tissue, and thus this reference teaches away from using an Erbium:YAG laser for small body cavities such as salivary ducts and temporomandibular joints.

In fact, the present specification, page 5, line 26 to page 6, line 7, discusses the surprising finding of the present invention as claimed, in view of a man of the art's view of the detrimental potential heating effects of Er:YAG lasers, while such heating effects would be of no concern in typical uses of Er:YAG lasers for treating large cavities such as kidneys, where the bulk of tissue and liquids can absorb part of the heat.

Thus, heating of the cavity is a potential issue for small body cavities, but not of concern with a large body cavity, so any potential efficiency increase that may be suggested by the Teichman reference for urinary calculi would be considered by a man of the art to be offset by the potential thermal damage to tissue in the confined space and limited water available for absorption of heat in the context of small body cavities such as salivary ducts and temporomandibular joints.

Furthermore, as clearly stated in the Teichman reference, page 878, left column, 2<sup>nd</sup> and 3<sup>rd</sup> paragraph, even if this reference were combined with the ADKIT reference, no clinical-grade Er:YAG laser is in fact disclosed, and therefore the combination would not disclose a method for treatment of hard tissue present in a fluid-filled body cavity, wherein the fluid-filled body cavity is selected from salivary ducts and temporomandibular joints, the method comprising: applying to said hard tissue, or to the proximity of said hard tissue, a laser beam produced by an Er:YAG laser device.

It is therefore respectfully submitted that claims 1-20 are novel and inventive over all the cited references.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 07-1337 and please credit any excess fees to such deposit account.

Respectfully submitted,

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